DEFENDANT

JANSSEN PHARMACEUTICA LP

TWENTY-SECOND JUDICIAL CIRCUIT

(St. Louis City)

LISA THOMPSON

PETITIONER/PLAINTIFF

ΔS

JANSSEN PHARMACEUTICA LP

RESPONDENT/DEFENDANT

ALIAS SUMMONS

NO.052-10141 DIV.

THE STATE OF MISSOURI TO DEFENDANT:

WHICH IS ATTACHED HERETO, AND TO SERVE A COPY OF YOUR PLEADING YOU ARE HEREBY SUMMONED TO APPEAR BEFORE THE ABOVE NAMED COURT AND TO FILE YOUR PLEADING TO THE PETITION, COPY OF FOR THE PETITIONER WHOSE ADDRESS IS UPON ATTORNEY HAGEMAN, TODD S

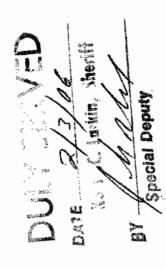
701 MARKET STREET, SUITE 1450, ST LOUIS, MO 63101-

ALL WITHIN 30 DAYS AFTER SERVICE OF THIS SUMMONS UPON YOU, EXCLUSIVE WILL BE TAKEN AGAINST YOU FOR THE RELIEF DEMANDED IN THE PETITION OF THE DAY OF SERVICE. IF YOU FAIL TO DO SO, JUDGEMENT BY DEFAULT

SEAL THERE OF HEREUNTO AFFIXED, AT ST. LOUIS, MISSOURI, THIS WITNESS, MARIANO V. FAVAZZA, CLERK OF SAID COURT, WITH THE 19TH DAY OF JANUARY, 2006

PLAINTIFF 2 SUMMONS Sheriff of MERCER COUNTY In the case of No. 052-10141 \$ THOMPSON CIVIL Div. LISA

1125 TRENTON HARBOURTON ROAD JANSSEN PHARMACEUTICA LP TITUSVILLE NJ 08560



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Sta	te of Missouri}	
Cit	} SS y of St. Louis } RETURN OF SERV	ICE OF SUMMONS
	I HEREBY CERTIFY THAT I SI	ERVED THE WITHIN SUMMONS:
(1)	By delivering on the day of summons and a copy of the most recent petition to the w defendant/respondent	at am/pm a copy of the rithin-named by personal service at:
(2)	By leaving a copy on the day of defendant/respondent at	,atam/pm for the within-name with
	dwelling place or usual abode of said defendant/responde By the following	ent with someone in his/her family over age of 15 years.
	DIRECTIONS TO SHERIFF OR CLERK	
	A copy of the summons and petition must be served on each party. For method of service see Civil Rule 54.  A third party summons should be handled in the same manner as an ordinary summons except a copy of the original plaintiff's petition should be attached to the summons to be served on the third party defendant. SEE RULE 52.11	SHERIFF's FEE:  Summons ) Non-Est. ) Mileage ) Total )
	Service by mail is permitted only under conditions set forth in Rule 54. Clerk should insert in the summons names of only the defendant/respondent who are to be served by mail. After an affidavit has been filed as provided by Rule 54.16. it becomes the duty of the clerk to mail copies of the summons and the petition to DEFENDANT/RESPONDENT by registered or certified mail, requesting a return receipt signed by addressee only. The clerk shall also execute the certificate of mailing and file the summons, returned receipt, certified mail receipts within the file. SEE RULE 54.	I hereby certify that on the day of,, I mailed a copy of this summons and a copy of this petition to Defendant/Respondent by registered certified mail, requesting a return receipt signed by the addressee only, addressed to each of said Defendant/Respondent at the address furnished by petitioner.
	Service by First Class Mail may be made under section 506.150 RSMO By plaintiff or any person authorized to serve process under Section 506.140 RSMO.	
	All done in City/County Missouri Sheriff of City/County Missouri	

Ву\_\_

Deputy

MARIANO V. FAVAZZA, Circuit Clerk

Page: 3 of 24 PageID #: 8 Case: 4:06-cv-00253 Filed: 02/21/06

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TWENTY-SECOND JUDICIAL CIRCUIT

(St. Louis City)

LISA THOMPSON

JANSSEN PHARMACEUTICA LP

PETITIONER/PLAINTIFF

VS

RESPONDENT/DEFENDANT

ALIAS SUMMONS

NO.052-10141

THE STATE OF MISSOURI TO DEFENDANT:

WHICH IS ATTACHED HERETO, AND TO SERVE A COPY OF YOUR PLEADING YOU ARE HEREBY SUMMONED TO APPEAR BEFORE THE ABOVE NAMED COURT AND TO FILE YOUR PLEADING TO THE PETITION, COPY OF

UPON ATTORNEY HAGEMAN, TODD S

701 MARKET STREET, SUITE 1450, ST LOUIS, MO 63101 FOR THE PETITIONER WHOSE ADDRESS IS

LL WITHIN 30 DAYS AFTER SERVICE OF THIS SUMMONS UPON YOU, EXCLUSIVE ILL BE TAKEN AGAINST YOU FOR THE RELIEF DEMANDED IN THE PETITION F THE DAY OF SERVICE. IF YOU FAIL TO DO SO, JUDGEMENT BY DEFAULT

EAL THERE OF HEREUNTO AFFIXED, AT ST. LOUIS, MISSOURI, THIS ITNESS, MARIANO V. FAVAZZA, CLERK OF SAID COURT, WITH THE

19TH DAY OF JANUARY, 2006

Sheriff of MERCER COUNTY

CIVIL

No. 052-10141 Div. 13

SUMMONS

In the case of

LISA THOMPSON

PLAINTIFF

DEFENDANT JANSSEN PHARMACEUTICA LP

1125 TRENTON HARBOURTON ROAD JANSSEN PHARMACEUTICA LP 08560 TITUSVILLE NJ

MARIANO V BAVATTA Cumit Class

DEFENDANT

State of Missouri}		
	}	SS
City of St. Louis	}	

# RETURN OF SERVICE OF SUMMONS I HEREBY CERTIFY THAT I SERVED THE WITHIN SUMMONS:

(1)	By delivering on the day of summons and a copy of the most recent petition to the w defendant/respondent	
(2)	By leaving a copy on the day of defendant/respondent at	,atam/pm for the within-named with
(3)	dwelling place or usual abode of said defendant/responde By the following	ent with someone in his/her family over age of 15 years.
	DIRECTIONS TO SHERIFF OR CLERK	
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	Service by First Class Mail may be made under section 506.150 RSMO By plaintiff or any person authorized to serve process under Section 506.140 RSMO.	
]	All done inCity/County Missouri Sheriff ofCity/County Missouri By Deputy	

MARIANO V. FAVAZZA, Circuit Clerk



# MISSOURI CIRCUIT COURT TWENTY-SECOND JUDICIAL CIRCUIT

(ST. LOUIS CITY)

Plaintiff	}	
VS	)	Cause No.
Defendant	; }	Division I

#### SCHEDULING ORDER

The above-styled cause is designated as a "Track 1" case for scheduling purposes, subject to the deadlines set forth herein. All dates are calculated from the date of the petition's filing. Plaintiff shall make all relevant medical records and signed authorizations available for inspection and copying by Defendant's counsel, and at Defendant's cost, within five (5) days of defense counsel's entry of appearance. Plaintiff is expected to serve the standard interrogatories together with the Petition. Defendant (s) shall serve answers to the standard interrogatories within the time prescribed by the Missouri Supreme Court Rules of Civil Procedure. Defendant is to serve the standard interrogatories with counsel's entry of appearance. Plaintiff shall serve answers to the standard interrogatories within the time prescribed by the Missouri Supreme Court Rules of Civil Procedure.

Deviation from the Scheduling Order shall be only by consent of the parties or by 'eave of Court. Further, this Scheduling Order assumes prompt disposition of discovery disputes. The parties are strongly encouraged to resolve discovery disputes by mutual consent and without the need for Court intervention. In no event shall deviations from the deadlines in this Order or delays in resolving discovery disputes affect the "ready for trial" date set forth herein, except by Court order.

#### **TRACK 1: EXPEDITED**

60 Day	s:	All parties to have served initial written discovery.
90 Day	s:	All parties to have responded to initial written discovery.
100 Da	ys:	Disclosure of Plaintiff's experts.
120 Da	ys:	Plaintiff's experts' depositions completed.
135 Da	ys:	Disclosure of Defendant's experts.
155 Da	ys:	Defendant's experts' depositions completed.
160 Da	ys:	Council for all parties to file certificate of settlement negotiations.
165 Da	ys:	Disclosure of Plaintiff's rebuttal experts and supplementary disclosure of new experts or new opinions by all parties.
180 Da	ys:	All experts' depositions completed. No continuances will be granted after this date for incomplete discovery, absent

deemed ready for trial.

The Court encourages early mediation.

SO ORDERED

Presiding Judge

leave of Court for good cause shown. Case



# MISSOURI CIRCUIT COURT TWENTY-SECOND JUDICIAL CIRCUIT

(ST. LOUIS CITY)

Plaintiff	
vs	) Cause No
. ;	
Defendant	Division I
, <b>\</b>	

#### **SCHEDULING ORDER**

The above-styled cause is designated as a "Track 2" case for scheduling purposes, subject to the deadlines set forth herein. All dates are calculated from the date of the petition's filing. Plaintiff shall make all relevant medical records and signed authorizations available for inspection and copying by Defendant's counsel, and at Defendant's cost, within five (5) days of defense counsel's entry of appearance. Plaintiff is expected to serve the standard interrogatories together with the Petition. Defendant (s) shall serve answers to the standard interrogatories within the time prescribed by the Missouri Supreme Court Rules of Civil Procedure. Defendant is to serve the standard interrogatories within the time prescribed by the Missouri Supreme Court Rules of Civil Procedure.

Deviation from the Scheduling Order shall be only by consent of the parties or by leave of Court. Further, this Scheduling Order assumes prompt disposition of discovery disputes. The parties are strongly encouraged to resolve discovery disputes by mutual consent and without the need for Court intervention. In no event shall deviations from the deadlines in this Order or delays in resolving discovery disputes affect the "ready for trial" date set forth herein, except by Court order.

#### TRACK 2: STANDARD

100 Days:	All parties to have served initial written discovery.
130 Days:	All parties to have responded to initial written discovery.
180 Days:	Disclosure of Plaintiff's experts.
220 Days:	Plaintiff's experts' depositions completed.
265 Days:	Disclosure of Defendant's experts.
325 Days:	Defendant's experts' depositions completed.
330 Days:	Council for all parties to file certificate of settlement negotiations.
340 Days:	Disclosure of Plaintiff's rebuttal experts and supplementary disclosure of new experts or new opinions by all parties.
370 Days:	All experts' depositions completed. No continuances will be granted after this date for incomplete discovery, absent leave of Court for good cause shown. Case

deemed ready for trial.

The Court encourages early mediation.

SO ORDERED
Presiding Judge

RR-422 (ML10/4)



#### TWENTY-SECOND JUDICIAL CIRCUIT OF MISSOURI

Civil Courts Building, 10 N. Tucker Blvd. St. Louis, Missouri 63101

NOTICE OF MEDIATION PROGRAM AND SERVICES VOLUNTARY EARLY DISPUTE RESOLUTION PROGRAM CIRCUIT COURT OF THE CITY OF ST. LOUIS, MISSOURI TWENTY-SECOND JUDICIAL CIRCUIT

Pursuant to Missouri Supreme Court Rule 17, the Circuit Court of the City of St. Louis, Missouri (Twenty-Second Judicial Circuit) has adopted a local rule to encourage voluntary early dispute resolution. The purpose of the rule and the program of early dispute resolution it establishes is to foster timely, economical, fair and voluntary settlements of lawsuits without delaying or interfering with a party's rights to resolve a lawsuit by trial.

This program applies to all civil actions assigned to Division 1 and you are hereby notified that it is available for you in this case.

The program encourages the voluntary early resolution of disputes through mediation. Mediation is an informal non-binding alternative resolution process in which a trained mediator facilitates discussions and negotiations among the parties to help them resolve their dispute. The mediator is impartial and has no authority to render a decision or impose a resolution on the parties. During the course of the mediation, the mediator may meet with the parties together and separately to discuss the dispute, to explore the parties' interests, and to stimulate ideas for resolution of the dispute.

The Presiding Judge's Division Clerk keeps a list of mediators approved by the Court, and information regarding their qualifications, in the Division #1 courtroom. If all parties to the suit agree to mediation, within ten days after they have all filed the Consent to Mediation form on the reverse side of this page with the Clerk of the Court, they shall jointly select from that list a mediator who is willing and available to serve. If the parties cannot agree upon the mediator to be selected, the Court will make the selection.

The full text of the Circuit Court's Voluntary Early Dispute Resolution rule governing the conduct of the mediation is available from the Clerk of the Circuit Court. A copy of this notice is to be provided by the Clerk of the Circuit Court to each of the parties initiating the suit at the time it is filed, and a copy is to be served on each other party in the suit with the summons and petition served on that party.

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# **CONSENT TO MEDIATION FORM**

(To be completed, filed with the Clerk of the Court and served by each party on all other parties.)

# IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS STATE OF MISSOURI TWENTY-SECOND JUDICIAL CIRCUIT

	Plaintiff(s),	)
	, idinim(o),	) Cause No
vs.	and the second	) )
	Defendant(s),	)
	Defendant(3),	,
have discussed the	he subject of mediation	rd in this case, hereby certify that I under the Court's Voluntary Early ent(s) in this case and that:
(Check appropriat	te line)	•
to the re		d be helpful in this case and consent nediation upon the filing of similar the case.
We do n	not consent to the refer	ral of this case to mediation.
•		
	(Signature)	•
	(Print Name)	
	Attorney for:	•
	(Party or Parties)	
Date:		

[Flip side of Consent Mediation Form]

Case: 4:06-cv-00253 Doc. #: 1-4 Filed: 02/21/06 Page: 9 of 24 PageID #: 14

# IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS STATE OF MISSOURI

LISA THOMPSON.

Plaintiff.

Cause No. 052-1014/

v.

JANSSEN PHARMACEUTICA, L.P., ET AL

Division No. 1

COPY

Serve: Registered Agent for

Janssen Pharmaceutica, L.P. CT Corporation System 906 Olive St.

St. Louis, MO 63101

Defendants.

JURY TRIAL DEMANDED

# PLAINTIFF'S ORIGINAL PETITION

COMES NOW plaintiff, by and through his undersigned attorneys and for his persion against defendants states the following:

# **INTRODUCTION & PARTIES**

- 1. This is a civil action brought on behalf of Plaintiff regarding damages which occurred as a result of Plaintiff's ingestion of Risperdal® (Risperidone) ("Risperdal"). Risperdal was manufactured, marketed, distributed and sold to Plaintiff by Janssen Pharmaceutica, LP ("Janssen") and/or Janssen's representatives.
- 2. Plaintiff is an individual who is a citizen of the State of Missouri and a resident of Livingston County, Missouri.
- 3. Janssen is an American pharmaceutical company incorporated in the State of New Jersey, with its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. Janssen is duly authorized to conduct business in the State of Missouri. Service of process upon Janssen may be accomplished by serving the agent for service of process CT

Corporation System, 906 Olive St., St. Louis, Missouri 63101. Janssen does business by agent in Missouri and, on information and belief, at all times relevant advertised, marketed, promoted, sold and/or distributed Risperdal in Missouri.

4. At all times relevant herein, Janssen was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing pharmaceuticals, including Risperdal, and other products for use by the mainstream public, including Plaintiff.

## **JURISDICTION & VENUE**

- 5. This Court has jurisdiction over Janssen as the amount in controversy exceeds this Court's minimum jurisdictional limit and Janssen transacts business in Missouri and has engaged in a tortuous act in Missouri within the meaning of Mo. STAT. ANN. §506.500. This cause of action arose from said business transactions and tortuous acts.
- 6. Venue is proper pursuant to Mo. STAT. ANN. §508.050 and Mo. STAT. ANN. §508.010 as this is the County in which Plaintiff's cause of action accrued.

#### CONDITIONS PRECEDENT

7. Plaintiff has satisfied all conditions precedent to bringing this action.

#### **FACTS**

8. In September 1993 Janssen obtained approval from the U.S. Food and Drug Administration (hereinafter the "FDA") to market the prescription drug Risperidone ("Risperdal") for treatment of adults with schizophrenia with a target dosage of 4-6 mg/d. In December 2003, Risperdal was approved by the FDA for short-term treatment of acute manic or mixed episodes associated with Bipolar I Disorder with recommended doses of 1-6 mg/d.

- 9. Despite its limited approval for marketing, in twelve years Risperdal has become one of the world's best selling drugs. According to Janssen's Form 10K, 2004 worldwide Risperdal sales exceeded \$3 billion, which made Risperdal Janssen's second-highest selling drug. Further, 2004 sales of Risperdal were 21% higher than in 2003.
- 10. Janssen's own pre-clinical studies regarding Risperdal and medical literature related to antipsychotic drugs dating to the 1950s demonstrate that Risperdal and other antipsychotics cause weight gain and hyperglycemia.
- 11. On September 11, 2003, the FDA informed all manufacturers of atypical antipsychotic drugs, including Janssen, that due to an increasing prevalence of diabetes-related illnesses associated with this class of drugs, that all labeling must bear the following language in the Warnings section:

Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiologic studies suggest an increased risk of treatment emergent hyperglycemia-related adverse events in patients treated with atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available.

Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required

continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

- 12. In November 2003, Janssen was chastised by the FDA for a brazen, "false" and "misleading" 'dear healthcare provider' letter sent in conjunction with the September 2003 mandated change in Risperdal's labeling.
- 13. According to the FDA, Janssen's letter mislead doctors by failing to disclose the addition of information relating to hyperglycemia and diabetes mellitus to the labeling, minimizing the risks of potentially fatal hyperglycemia-related adverse events, failing to recommend regular glucose control monitoring to identify diabetes mellitus as soon as possible and misleadingly claiming that Risperdal is safer than other atypical antipsychotics.
- 14. The FDA requested that Janssen immediately cease the dissemination of promotional materials for Risperdal containing claims similar to the foregoing and provide a plan of action to correct the effects of its false and misleading letter.
- 15. Finally, the FDA admonished Janssen that the violations detailed above did not constitute an exhaustive list, ant that it was continuing to "evaluate other aspects" of Janssen's promotional campaign for Risperdal and could determine that "additional measures" would be necessary to "fully correct the false or misleading messages resulting from your [Janssen's] violative conduct."
- 16. Under applicable statutes and regulations, the manufacturer of a prescription drug regulated by the FDA may not promote or market the use of the drug for purposes or in dosages other than those approved by the FDA. Uses of a prescription drug for purposes other than those approved by the FDA are referred to as "off-label" uses. Promotion by a drug manufacturer of "off-label" uses of prescription drugs is strictly illegal and contrary to the explicit policies and regulations of the United States Government.

- 17. Upon information and belief, Janssen promoted Risperdal by employing the illegal direct solicitation of physicians for off-label uses; and making false statements to physicians and pharmacists concerning the efficacy and safety of Risperdal for off-label uses. As a result of Janssen's illegal scheme, Plaintiff was prescribed Risperdal for an unnecessary and off-label use.
- 18. There is no valid scientific evidence to support the contention that Risperdal is safe and effective for treatment of any off-label use. There is no valid scientific evidence concerning the therapeutic equivalence of Risperdal for any off-label use.
- 19. Janssen did business in the State of Missouri; made contracts to be performed in whole or in part in Missouri and/or manufactured, tested, sold, offered for sale, supplied or placed in the stream of commerce, or in the course of business materially participated with others in so doing, Risperdal, which Janssen knew to be defective, unreasonably dangerous and hazardous, and which Janssen knew would be substantially certain to cause injury to persons within the State thereby negligently and intentionally causing injury to persons within Missouri, and as described herein, committed and continues to commit tortuous and other unlawful acts in the State of Missouri.
- 20. Janssen sold or aided and abetted in the sale of Risperdal which was and is defective and unreasonably dangerous. At all pertinent times, Janssen knew, or should have known, that Risperdal was and is hazardous to human health.
- 21. Janssen, through its funding and control of certain studies concerning the effects of Risperdal on human health, their control over trade publications, promoting, marketing, and/or through other agreements, understandings and joint undertakings and enterprises, conspired with, cooperated with and/or assisted in the wrongful suppression, active concealment and/or

misrepresentation of the true relationship between Risperdal and various diseases, all to the detriment of the public health, safety and welfare and thereby causing harm to the State.

- 22. Specifically, and in addition to the allegations above, Janssen knew of the hazards associated with Risperdal; affirmatively and actively concealed information which clearly demonstrated the dangers of Risperdal and affirmatively misled the public and prescribing physicians with regard to the material and clear risks of Risperdal; they did so with the intent that prescribing physicians would continue to prescribe Risperdal; they then well knew that prescribing physicians would not be in a position to know the true risks of Risperdal; and they knew that prescribing physicians would rely upon the misleading information that they promulgated.
- 23. At all pertinent times, Janssen purposefully and intentionally engaged in these activities, and continues to do so, knowing full well that when the general public, including Plaintiff, use Risperdal as Janssen intended, that Plaintiff would be substantially certain to suffer disease, injury and sickness.
- 24. The statements, representations and promotional schemes publicized by Janssen were deceptive, false, incomplete, misleading and untrue. Janssen knew, or should have known, that its statements, representations and advertisements were deceptive, false, incomplete, misleading and untrue at the time of making such statements. Janssen had an economic interest in making such statements. Neither the Plaintiff nor the physicians in Missouri who prescribed Risperdal had knowledge of the falsity or untruth of Janssen's statements, representations and advertisements when prescriptions for Risperdal were written; moreover, the Plaintiff and the Plaintiff's physician had a right to rely on Janssen's statements, representations and advertisements. Each of the statements, representations and advertisements were material to the

Plaintiff's purchase of Risperdal in that the Plaintiff would not have purchased Risperdal if Plaintiff had known that Janssen's statements, representations and advertisements were deceptive, false, incomplete, misleading and untrue.

- 25. Plaintiff had a right to rely upon the representations of Janssen and was directly and proximately injured by such reliance, all as described above.
- 26. Had Plaintiff been adequately warned of the potential life-threatening side effects, Plaintiff could have chosen to request other prescription medications and avoided Risperdal's potential life-threatening side effects.
  - 27. Plaintiff was diagnosed with diabetes while taking Risperdal.

#### **ALLEGATIONS**

- 28. Janssen negligently, recklessly and wantonly failed to warn Plaintiff, and the general public, of the risks associated with taking Risperdal. Janssen failed to do so even <u>after</u> various studies, including their own, showed that there were problems concerning the risks of diabetes and diabetes-related injuries associated with Risperdal.
- 29. Janssen endeavored to deceive Plaintiff, and the general public, by not disclosing the findings of the various studies, including its own, that revealed problems concerning the dangers of Risperdal.
- 30. Further, Janssen did not provide warnings and instructions that would have put Plaintiff, and the general public, on notice of the dangers and adverse effects caused by Risperdal.
- 31. Janssen designed, manufactured, distributed, sold and/or supplied Risperdal into the stream of commerce in a defective and unreasonably dangerous condition, taking into consideration the utility of the drug and the risk to Plaintiff and the general public.

- 32. Risperdal as designed, manufactured, distributed, sold and/or supplied by Janssen was defective as marketed due to inadequate warnings, instructions and/or labeling.
- 33. Risperdal as designed, manufactured, distributed, sold and/or supplied by Janssen was defective due to inadequate testing before and after Janssen's knowledge of the various studies, including their own, evidencing the rightful concerns over the risks of diabetes and diabetes-related injuries associated with Risperdal.

#### FRAUDULENT CONCEALMENT

34. Defendants are estopped from asserting a statute of limitations defense because they fraudulently concealed from Plaintiff the nature of Plaintiff's injury and the connection between the injury and Risperdal.

## CAUSES OF ACTION

#### I. STRICT PRODUCTS LIABILITY

35. Janssen is liable as the manufacturer, distributor and/or seller of the drug Risperdal because Risperdal, when sold, was in a defective and unreasonably dangerous condition. Janssen owed a strict duty to Plaintiff not to harm him/her through the use of the drug Risperdal.

#### A. DESIGN DEFECT

36. Risperdal was defective in design and/or formulation in that, when it left the hands of Janssen and/or its representatives, the foreseeable risks of serious harm posed by the drug outweighed its alleged benefits. The foreseeable risks of serious harm were so great that Plaintiff, and the general public, having known of such foreseeable risks and alleged benefits, would not have ingested Risperdal.

- 37. Risperdal was placed into the stream of commerce by Janssen acting through authorized agents, servants, employees and/or representatives. Plaintiff was prescribed Risperdal by Plaintiff's physician and used the drug in a manner reasonably foreseeable by Janssen.
- 38. The Risperdal ingested by Plaintiff was expected to and did reach Plaintiff without substantial change in its condition as tested, manufactured, designed, labeled, packaged, marketed and distributed. As a result of the use of Risperdal, Plaintiff suffered severe, permanent and disabling injuries and related damages.

#### B. Marketing Defect-Inadequate and Improper Warnings

- 39. Risperdal was marketed to physicians to be prescribed to their patients and was marketed and advertised directly to the consuming public. Risperdal, as manufactured and supplied to healthcare professionals and the general public, was unaccompanied by proper warnings regarding the serious risks of ingesting the drug. Further, Janssen failed to warn of these serious risks after Janssen had knowledge of same. The information provided to consumers did not reflect Janssen's knowledge that Risperdal was not safe and effective as indicated in its aggressive marketing campaign, nor were consumers made aware that ingesting the drug could result in serious injury, pain and discomfort and/or death. Full and proper warnings that accurately and fully reflected the risks of serious injury and/or sudden death due to the ingestion of Risperdal should have been disclosed by Janssen.
- 40. Plaintiff was prescribed Risperdal by Plaintiff's physician who used the drug in a manner reasonably foreseeable by Janssen. Risperdal was expected to and did reach Plaintiff without substantial change in its condition as tested, manufactured, designed, labeled, packaged, marketed and distributed. Plaintiff was not aware of, and could not have reasonably discovered, the unreasonably dangerous nature of Risperdal.

41. As the producing cause and legal and direct result of the failure to warn consumers of the defective condition of Risperdal, as manufactured and/or supplied by Janssen and its representatives, Plaintiff has suffered severe, permanent and disabling injuries and related damages.

# II. UNLAWFUL MERCHANDISING PRACTICES

- 42. Janssen is a person as defined by Mo. STAT. ANN. § 407.010. Janssen was, at the time of the occurrence, and is now, engaged in the business of designing, manufacturing, marketing, distributing pharmaceutical drugs, for sale to and use by consumers.
- 43. Janssen committed wrongful acts, both knowingly and unconscionably, toward Plaintiff. Specifically, Janssen represented that Risperdal was a safe and effective drug when, in fact, it was not. Janssen omitted material facts in the sale and advertisement of merchandise to Plaintiff concerning Risperdal that was known at the time Risperdal was prescribed to Plaintiff with the intent to induce Plaintiff's use of Risperdal. Plaintiff would not have taken Risperdal if the information withheld by Janssen regarding the serious risks involved with ingesting Risperdal had been disclosed.
- 44. The foregoing wrongful actions by Janssen caused Plaintiff to suffer injuries and monetary damages.

### III. FRAUD

45. Janssen made material representations that were false and that were either known to be false when made or were asserted without knowledge of their truth. Janssen had in its possession adverse drug event reports, drug studies, and other documentation about Risperdal and yet made the following misrepresentations:

- Misrepresentations regarding the frequency of Risperdal-related adverse event reports or occurrences in the Risperdal label, package insert or PDR label;
- Misrepresentations as to the existence, occurrence and frequency of occurrences, severity and extent of the overall risks of Risperdal;
- Misrepresentations as to the efficacy of Risperdal;
- Misrepresentations as to the number of adverse events and deaths reported with the use of Risperdal;
- Misrepresentations regarding the nature, seriousness, and severity of adverse events reported with the use of Risperdal.
- 46. Janssen intended that these misrepresentations be relied upon by physicians, including Plaintiff's physician, healthcare providers and consumers. Plaintiff did rely upon the misrepresentations that caused Plaintiff's injuries.
- 47. Janssen's misrepresentations were the proximate and/or producing cause of Plaintiff's injuries.

#### IV. NEGLIGENCE

- 48. Janssen owed Plaintiff legal duties in connection with its development, manufacture, and distribution of Risperdal. Janssen breached those duties, proximately causing Plaintiff's injuries. Specifically, Janssen failed to meet its duty to use reasonable care in the testing, creating, designing, manufacturing, labeling, packaging, marketing, selling, and warning of Risperdal. Janssen is liable for acts and/or omissions amounting to negligence, gross negligence and/or malice including, but not limited to the following:
  - Failure to adequately warn Plaintiff and Plaintiff's physician of the known or reasonably foreseeable danger that Plaintiff would suffer a serious injury or death by ingesting Risperdal;

- Failure to adequately warn Plaintiff and Plaintiff's physician of the known or reasonably foreseeable danger that Plaintiff would suffer a serious injury or death by ingesting Risperdal in unsafe doses;
- Failure to use reasonable care in testing and inspecting Risperdal so as to ascertain whether or not it was safe for the purpose for which it was designed, manufactured and sold;
- Failure to use reasonable care in implementing and/or utilizing a reasonably safe design in the manufacture of Risperdal;
- Failure to use reasonable care in the process of manufacturing Risperdal in a reasonably safe condition for the use for which it was intended;
- Failure to use reasonable care in the manner and method of warning Plaintiff and Plaintiff's physician as to the danger and risks of using Risperdal in unsafe doses;
- Such further acts and/or omissions that may be proven at trial.
- 49. The above-described acts and/or omissions of all Defendants were a direct and proximate cause of the severe, permanent and disabling injuries and resulting damages to Plaintiff.

# V. <u>Negligent Misrepresentation</u>

- 50. Janssen failed to communicate to Plaintiff and/or the general public that the ingestion of Risperdal could cause serious injuries after it became aware of such risks. Instead, Janssen represented in its marketing that Risperdal was safe and effective.
- 51. Plaintiff brings this cause of action against Janssen under the theory of negligent misrepresentation for the following reasons:
  - Janssen, individually, and through its agents, representatives, distributors
    and/or employees, negligently misrepresented material facts about
    Risperdal in that they made such misrepresentations when they knew or
    reasonably should have known of the falsity of such misrepresentations.
    Alternatively, Janssen made such misrepresentations without exercising
    reasonable care to ascertain the accuracy of these representations;

- The above misrepresentations were made to Plaintiff, as well as the general public;
- Plaintiff and her healthcare provider justifiably relied on Janssen's misrepresentations; and
- Consequently, Plaintiff ingested Risperdal to Plaintiff's detriment, Janssen's negligent misrepresentations proximately caused Plaintiff's injuries and monetary losses.

#### VI. MISREPRESENTATION

- 52. Janssen is engaged in the business of selling Risperdal. By its advertising, labels, or otherwise, Janssen has made to Plaintiff, and the public, a misrepresentation of a material fact concerning the character or quality of Risperdal.
- 53. Plaintiff justifiably relied on Janssen's misrepresentations in purchasing Risperdal. Plaintiff has suffered physical harm proximately caused by Janssen's misrepresentations regarding the character or quality of Risperdal.

#### VII. EXPRESS WARRANTY

- 54. Janssen is a merchant and/or seller of Risperdal. Janssen sold Risperdal to consumers, including Plaintiff, for the ordinary purpose for which such drugs are used by consumers. Janssen made representations to Plaintiff about the quality or characteristics of Risperdal by affirmation of fact, promise and/or description.
- 55. The representations by Janssen became part of the basis of the bargain between Janssen and Plaintiff. Risperdal did not comport with the representations made by Janssen in that it was not safe for the use for which it was marketed. Plaintiff has notified Janssen that Janssen has breached its express warranty. This breach of duty by Janssen was a proximate cause of the injuries and monetary loss suffered by Plaintiff.

## VIII. IMPLIED WARRANTY

#### A. WARRANTY OF MERCHANTABILITY

56. Janssen is a merchant and/or seller of Risperdal. Plaintiff purchased Risperdal from Janssen and used Risperdal for the ordinary purpose for which it is used by consumers. At the time it was purchased by Plaintiff, Risperdal was not fit for the ordinary purpose for which such drugs are used. Risperdal was not fit for the ordinary purpose for which such drugs are used because it was not manufactured, designed or marketed in a manner to accomplish its purpose safely. Janssen's breach of its implied warranty of merchantability caused Plaintiff's injuries and monetary losses.

#### B. WARRANTY OF FITNESS

- 57. Janssen sold Risperdal to Plaintiff with the knowledge that Plaintiff was purchasing Risperdal for a particular purpose. Further, Janssen knew, or should have known, that Plaintiff was relying on Janssen's skill or judgment to select goods fit for Plaintiff's purpose.
- 58. Janssen delivered goods that were unfit for Plaintiff's particular purpose, and thus breached its implied warranty of fitness. Plaintiff has notified Janssen of Janssen's breach of the implied warranty of fitness.
- 59. Janssen's failure to select and sell a product which was reasonably safe for its intended use proximately caused Plaintiff's injuries and monetary losses.

#### **DAMAGES**

60. Upon the trial of this case, it will be shown that Plaintiff was caused to sustain serious injuries and damages as a proximate result of Janssen's conduct. Plaintiff will respectfully request the Court and Jury to determine the amount of the loss Plaintiff has incurred

in the past and will incur in the future, not only from a financial standpoint, but also in terms of good health and freedom from pain and worry.

#### PUNITIVE DAMAGES

At all times relevant hereto, Janssen actually knew of the defective nature of Risperdal as set forth herein and continued to design, manufacture, market, distribute and sell Risperdal so as to maximize sales and profits at the expense of the public's health and safety and in conscious disregard of the foreseeable serious harm caused by Risperdal. Janssen's conduct exhibits such an entire want of care as to establish that its actions were a result of fraud, ill will, recklessness, and/or willful and intentional disregard for the safety and rights of Plaintiff, as well as the general public and/or consumers of Risperdal. Plaintiff is therefore entitled to punitive damages.

# JURY DEMAND

62. Plaintiff hereby requests a trial by jury on all issues in this case.

#### PRAYER

WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that upon trial hereof, the Court grant:

- Judgment against Defendants for actual damages, as set forth above, in an amount in excess of the minimum jurisdictional limits of this Honorable Court;
- 2. Interest on said Judgment, at the legal rate from the date of the Judgment;
- Plaintiff's costs of this suit;
- Prejudgment interest as allowed by law;

- 5. Any additional damages and punitive damages under the facts set forth in this or any amended pleading(s); and
- 6. Such other and further relief to which Plaintiff may be justly entitled, both in law and in equity.

Respectfully submitted,

By: Joseph J. Ninger

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